



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 09/885,731 | 06/20/2001 | Glen H. Erikson | E1047/20056 | 6800 |
| 3000 | 7590 | 12/02/2003 | EXAMINER | |
| CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 12TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212 | | | CHUNDURU, SURYAPRABHA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |

DATE MAILED: 12/02/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/885,731

Applicant(s)

ERIKSON ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-55 is/are pending in the application.
- 4a) Of the above claim(s) 28 and 30-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-27 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 16) filed on June 2, 2003 has been entered.
2. The Information Disclosure Statement (Paper No. 17) filed on July 23, 2003, has been entered and considered.
3. The terminal disclaimer (Paper No. 18) filed on July 23, 2003, has been entered.
4. This application is filed on June 20, 2001 and claims priority to US Patent application Nos. 09/664,827, filed on September 19, 2000, 09/613,263 filed on July 10, 2000, and 09/468,679, filed on December 21, 1999.

Response to Arguments

5. Applicant's response to the office action (Paper No.16) is fully considered and is found persuasive in view of arguments and IDS submitted.
6. With reference to the rejection maintained in the previous office action under 35 U.S.C. 112, first paragraph, applicants' arguments and IDS have been fully considered and the rejection is moot in view of the arguments and enablement of Watson-Crick base pairing involving more than two strands of DNA as shown in IDS.
7. With reference to the rejection made in the previous office action under obviousness-type double patenting, applicants' arguments and terminal disclaimer are fully considered and the rejection is withdrawn in view of the terminal disclaimer (Paper No. 16).
8. With reference to the rejection made in the previous office action under 35 USC 102(e) applicant's amendment and arguments are fully considered and the rejection is withdrawn in view of the amendment (Paper No. 16).

New Grounds of rejection

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-27, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over George Jr. (USPN. 5,451,502) in view of McGavin et al. (J. Mol. Graphics, Vol. 7, pages 218-232, 1989).

George Jr. teaches method for creating a nucleic acid multiplex of claims 1, 2, 4, and 29 (see column 3, lines 49-67, column 4, lines 1-35) wherein the method comprises

(a) creating a mixture comprising water (buffer), a Watson-Crick duplex (double-stranded nucleic acid) (see column 3, lines 49-61, column 4, lines 1-16), a number of single-stranded mixed base sequence molecules (probe or oligonucleotide containing at least a nucleobase sequence) (see column 3, lines 49-58), at least one accelerator agent (label) and

Art Unit: 1637

(b) incubating the reaction mixture to form said multiplex (see column 4, lines 10-16).

George Jr. also teaches that the probe comprises 5-57 nucleotides and target contains unlimited number of bases (see column 6, lines 1-24, column 9, lines 11-23);

With regard to claims 9-11, George Jr., teaches that the method comprises water, accounting for volume basis of the mixture, ranging from 50% to 90% (see column 9, lines 45-51);

With regard to claims 12-14, George Jr. teaches that the method was carried out at temperatures ranging from 2-60⁰ C and pH of the hybridization buffer of about 5 to about 9 (see column 8, lines 34-53, column 10, lines 4-22, column 11, lines 65-68, column 12, lines 1-61);

With regard to claims 15-17, George Jr., teaches that the method comprises cations such as Na⁺, Mg²⁺, in a concentration ranging 50 mM to 100mM for NaCl, 5-10mM for MgCl₂ (see column 8, lines 35-53, column 9, lines 36-51);

With regard to claims 21-22, George Jr. teaches a flurophore label fluorescence, chemiluminescence label comprising rodhamine and fluorescein (see column 7, lines 1-19); A flurophore label with detectable marker using an atom, an inorganic radical (comprise monovalent cation), heavy metal (transition metals) (divalent or valency grater than 1), biotin and like (see column 6, lines 25-46);

With regard to claims 24-27, the accelerator agent is an organic liquid soluble in water (DMSO, formamide, ethylene glycol, glycerine) (see column 9, lines 40-44);

However George Jr. did not specifically teach that the each strand of said multiplex structure (probe-target complex) is related to all other strands of the multiplex by Watson-Crick base-pairing rules.

McGavin et al. teach formation of a multiplex structure of claims 1-5, 7-27, 29, wherein McGavin et al. disclose a multiplex structure comprising a first, a second, a third and a fourth sequence of nucleobases wherein four strands interact specifically with each other forming a multiplex structure through Watson-Crick pairing (see page 226, column 1, paragraphs 2-4) in which Watson-Crick duplexes are paired specifically about a dyad axis coincident with a common long molecular axis and with major grooves in continuous and specific contact (see page 230, column 1, paragraphs 1-3, page 225, column 1, paragraph 2, column 2, paragraph 3).

McGavin et al. teach that the multiplex structure comprises an artificial or synthetic quadruplex (see page 228, column 1, paragraphs 2-4); the multiplex structure comprises a nucleic acid (DNA and RNA) (see page 225, column 2, paragraph 3); in the multiplex structure any one strand alternates between two strands in anti-parallel orientation (see page 220, color plate 3a and 3b, page 228, column 2, paragraphs 3-8); Watson-Crick duplexes are paired specifically about a dyad axis coincident with a common long molecular axis and with major grooves in continuous and specific contact indicating major groove of first-second strand duplex is placed in the major groove of third-fourth strand duplex (see page 230, column 1, paragraphs 1-3, page 225, column 1, paragraph 2, column 2, paragraph 3);

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of forming or creating a multiplex as taught by George Jr. with the inclusion of Watson-Crick base pairing forming model as taught by McGavin et al. in order to obtain the invention as a whole. An ordinary artisan would have motivated to have added the structural stability of Watson-Crick base pairing of nucleic acid strands in a multiplex structure to the method of George Jr., because McGavin et al. taught Watson-Crick

Art Unit: 1637

kind of base pairing as a strong specific interaction between complementary strands and its growing significance in genetic recombination or specificity of interaction between strands. Therefore an ordinary artisan would have recognized the expected benefits of stability of Watson-Crick kind of base pairing structures and would have motivated to add the limitation to the method of forming a multiplex as taught by George Jr. to obtain a more stable multiplex structure.


Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
November 25, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER